RULE-MAKING ORDER

CR-103 (June 2004)
(Implements RCW 34.05.360)

Agency: Department of Health- Medical Quality Assurance Commission.

☒ **Permanent Rule**
☐ **Emergency Rule**

Effective date of rule:
Permanent Rules
☐ 31 days after filing.
☒ Other (specify) 03/01/2007 **(If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)**

Effective date of rule:
Emergency Rules
☐ Immediately upon filing.
☐ Later (specify)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?
☐ Yes ☒ No If Yes, explain:

Purpose: WAC 246-919-605 and WAC 246-918-125 defines the use of Laser, Light, Radiofrequency and Plasma (LLRP) devices by physicians (MD) and physician assistants (PA), specifies who can operate a device, specifies who the MD or PA can delegate the use of a devices to and outlines the degree of supervision required after delegation. The proposed new sections will protect the public from being harmed by unsupervised and untrained persons using LLRP.

Citation of existing rules affected by this order:
Repealed: None
Amended: None
Suspended: None

Statutory authority for adoption: RCW 18.71.017 and RCW 18.71A.020

Other authority : RCW 18.130.050(12)

PERMANENT RULE ONLY (Including Expedited Rule Making)
Adopted under notice filed as WSR 06-15-130 on 07/19/2006 (date).
Describe any changes other than editing from proposed to adopted version: The adopted rule is not different from the text of the proposed rule. However, in response to the feedback from the public and constituents, the Commission has elected to delay the effective date until March 1, 2007. For those that are currently not in compliance this will give them time to do so.

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

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EMERGENCY RULE ONLY
Under RCW 34.05.350 the agency for good cause finds:
☐ That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.
☐ That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding:

Date adopted: 08/25/2006

NAME (TYPE OR PRINT)
Blake T. Maresh

SIGNATURE

TITLE
Executive Director

CODE REVISER USE ONLY

CODE REVISER'S OFFICE
STATE OF WASHINGTON
FILED

JAN 24 2007

TIME 1:23 AM PM
WSR 07-03-111

(COMPLETE REVERSE SIDE)

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	0	Amended	0	Repealed	0
Federal rules or standards:	New	0	Amended	0	Repealed	0
Recently enacted state statutes:	New	0	Amended	0	Repealed	0

The number of sections adopted at the request of a nongovernmental entity:

New	0	Amended	0	Repealed	0

The number of sections adopted in the agency's own initiative:

New	2	Amended	0	Repealed	0

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	0	Amended	0	Repealed	0

The number of sections adopted using:

Negotiated rule making:	New	0	Amended	0	Repealed	0
Pilot rule making:	New	0	Amended	0	Repealed	0
Other alternative rule making:	New	2	Amended	0	Repealed	0

NEW SECTION

WAC 246-918-125 Use of laser, light, radiofrequency, and plasma devices as applied to the skin. (1) For the purposes of this rule, laser, light, radiofrequency, and plasma devices (hereafter LLRP devices) are medical devices that:

(a) Use a laser, noncoherent light, intense pulsed light, radiofrequency, or plasma to topically penetrate skin and alter human tissue; and

(b) Are classified by the federal Food and Drug Administration as prescription devices.

(2) Because an LLRP device penetrates and alters human tissue, the use of an LLRP device is the practice of medicine under RCW 18.71.011. The use of an LLRP device can result in complications such as visual impairment, blindness, inflammation, burns, scarring, hypopigmentation and hyperpigmentation.

(3) Use of medical devices using any form of energy to penetrate or alter human tissue for a purpose other than the purpose set forth in subsection (1) of this section constitutes surgery and is outside the scope of this section.

PHYSICIAN ASSISTANT RESPONSIBILITIES

(4) A physician assistant must be appropriately trained in the physics, safety and techniques of using LLRP devices prior to using such a device, and must remain competent for as long as the device is used.

(5) A physician assistant may use an LLRP device so long as it is with the consent of the sponsoring or supervising physician, it is in compliance with the practice arrangement plan approved by the commission, and it is in accordance with standard medical practice.

(6) Prior to authorizing treatment with an LLRP device, a physician assistant must take a history, perform an appropriate physical examination, make an appropriate diagnosis, recommend appropriate treatment, obtain the patient's informed consent (including informing the patient that a nonphysician may operate the device), provide instructions for emergency and follow-up care, and prepare an appropriate medical record.

PHYSICIAN ASSISTANT DELEGATION OF LLRP TREATMENT

(7) A physician assistant who meets the above requirements may delegate an LLRP device procedure to a properly trained and licensed professional, whose licensure and scope of practice allow the use of an LLRP device provided all the following conditions are met:

(a) The treatment in no way involves surgery as that term is understood in the practice of medicine;

(b) Such delegated use falls within the supervised professional's lawful scope of practice;

(c) The LLRP device is not used on the globe of the eye; and

(d) The supervised professional has appropriate training in, at a minimum, application techniques of each LLRP device, cutaneous medicine, indications and contraindications for such procedures, preprocedural and postprocedural care, potential complications and infectious disease control involved with each treatment.

(e) The delegating physician assistant has written office protocol for the supervised professional to follow in using the LLRP device. A written office protocol must include at a minimum the following:

(i) The identity of the individual physician assistant authorized to use the device and responsible for the delegation of the procedure;

(ii) A statement of the activities, decision criteria, and plan the supervised professional must follow when performing procedures delegated pursuant to this rule;

(iii) Selection criteria to screen patients for the appropriateness of treatments;

(iv) Identification of devices and settings to be used for patients who meet selection criteria;

(v) Methods by which the specified device is to be operated and maintained;

(vi) A description of appropriate care and follow-up for common complications, serious injury, or emergencies; and

(vii) A statement of the activities, decision criteria, and plan the supervised professional shall follow when performing delegated procedures, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician assistant concerning specific decisions made. Documentation shall be recorded after each procedure, and may be performed on the patient's record or medical chart.

(f) The physician assistant is responsible for ensuring that the supervised professional uses the LLRP device only in accordance with the written office protocol, and does not exercise independent medical judgment when using the device.

(g) The physician assistant shall be on the immediate premises during any use of an LLRP device and be able to treat complications, provide consultation, or resolve problems, if indicated.

NEW SECTION

WAC 246-919-605 Use of laser, light, radiofrequency, and plasma devices as applied to the skin. (1) For the purposes of this rule, laser, light, radiofrequency, and plasma devices (hereafter LLRP devices) are medical devices that:

(a) Use a laser, noncoherent light, intense pulsed light, radiofrequency, or plasma to topically penetrate skin and alter human tissue; and

(b) Are classified by the federal Food and Drug Administration as prescription devices.

(2) Because an LLRP device penetrates and alters human tissue, the use of an LLRP device is the practice of medicine under RCW 18.71.011. The use of an LLRP device can result in complications such as visual impairment, blindness, inflammation, burns, scarring, hypopigmentation and hyperpigmentation.

(3) Use of medical devices using any form of energy to penetrate or alter human tissue for a purpose other than the purpose set forth in subsection (1) of this section constitutes surgery and is outside the scope of this section.

PHYSICIAN RESPONSIBILITIES

(4) A physician must be appropriately trained in the physics, safety and techniques of using LLRP devices prior to using such a device, and must remain competent for as long as the device is used.

(5) A physician must use an LLRP device in accordance with standard medical practice.

(6) Prior to authorizing treatment with an LLRP device, a physician must take a history, perform an appropriate physical examination, make an appropriate diagnosis, recommend appropriate treatment, obtain the patient's informed consent (including informing the patient that a nonphysician may operate the device), provide instructions for emergency and follow-up care, and prepare an appropriate medical record.

(7) Regardless of who performs LLRP device treatment, the physician is ultimately responsible for the safety of the patient.

(8) Regardless of who performs LLRP device treatment, the physician is responsible for assuring that each treatment is documented in the patient's medical record.

(9) The physician must ensure that there is a quality assurance program for the facility at which LLRP device procedures are performed regarding the selection and treatment of patients. An appropriate quality assurance program shall include the following:

(a) A mechanism to identify complications and untoward effects of treatment and to determine their cause;

(b) A mechanism to review the adherence of supervised

professionals to written protocols;

(c) A mechanism to monitor the quality of treatments;

(d) A mechanism by which the findings of the quality assurance program are reviewed and incorporated into future protocols required by subsection (10)(d) of this section and physician supervising practices; and

(e) Ongoing training to maintain and improve the quality of treatment and performance of treating professionals.

PHYSICIAN DELEGATION OF LLRP TREATMENT

(10) A physician who meets the above requirements may delegate an LLRP device procedure to a properly trained and licensed professional, whose licensure and scope of practice allow the use of an LLRP device, provided all the following conditions are met:

(a) The treatment in no way involves surgery as that term is understood in the practice of medicine;

(b) Such delegated use falls within the supervised professional's lawful scope of practice;

(c) The LLRP device is not used on the globe of the eye;

(d) A physician has a written office protocol for the supervised professional to follow in using the LLRP device. A written office protocol must include at a minimum the following:

(i) The identity of the individual physician authorized to use the device and responsible for the delegation of the procedure;

(ii) A statement of the activities, decision criteria, and plan the supervised professional must follow when performing procedures delegated pursuant to this rule;

(iii) Selection criteria to screen patients for the appropriateness of treatments;

(iv) Identification of devices and settings to be used for patients who meet selection criteria;

(v) Methods by which the specified device is to be operated and maintained;

(vi) A description of appropriate care and follow-up for common complications, serious injury, or emergencies; and

(vii) A statement of the activities, decision criteria, and plan the supervised professional shall follow when performing delegated procedures, including the method for documenting decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made;

(e) The supervised professional has appropriate training in, at a minimum, application techniques of each LLRP device, cutaneous medicine, indications and contraindications for such procedures, preprocedural and postprocedural care, potential complications and infectious disease control involved with each treatment;

(f) The delegating physician ensures that the supervised professional uses the LLRP device only in accordance with the written office protocol, and does not exercise independent medical judgment when using the device;

(g) The delegating physician shall be on the immediate premises during the patient's initial treatment and be able to treat complications, provide consultation, or resolve problems, if indicated. The supervised professional may complete the initial treatment if the physician is called away to attend to an

emergency;

(h) Existing patients with an established treatment plan may continue to receive care during temporary absences of the delegating physician provided that there is a local back-up physician who satisfies the requirements of subsection (4) of this section. The local back-up physician must agree in writing to treat complications, provide consultation or resolve problems if medically indicated. The local back-up physician shall be reachable by phone and able to see the patient within sixty minutes.

(11) The use of, or the delegation of the use of, an LLRP device by a physician assistant is covered by WAC 246-918-125.